

REMARKS

Claims 24-26 remain pending in the present application wherein claim 26 is indicated as containing allowable subject matter. Claims 27-29 have been cancelled without prejudice or disclaimer of the subject matter therein.

REJECTION UNDER §102

Claims 27- 29 have been rejected under 35 U.S.C. §102(b) or §102(e) as being anticipated by Barnes (U.S. 4,721,723) or Ward et al. (U.S. 5,872,132). This rejection has been rendered moot by the above-amendment. Having obviated the rejection, reconsideration and withdrawal are respectfully requested.

REJECTION UNDER §103

Claims 24 and 25 have been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Stemp et al. (EP 190,496) in view of Barnes et al. (U.S. 4,721,723). This rejection is respectfully traversed.

The Examiner asserts that Stemp pages 51-52 teach a process for making paroxetine hydrochloride from organic acid salts of paroxetine and that page 3 teaches that methane sulfonic acid is an acceptable acid for paroxetine salt formation. The Examiner concludes that it would have been obvious to create paroxetine methane sulfonate and to use the same to form paroxetine hydrochloride. The Examiner supports this conclusion by referring to Barnes which purportedly shows that paroxetine hydrochloride is conventionally prepared from other organic salts, citing examples 2, 3, and 8. The Examiner's position is in error for several reasons.

First, contrary to the Examiner's statement, Stemp pages 51-52 does not teach the formation of paroxetine hydrochloride from any organic acid salt. Instead of being a generic disclosure to organic salts, this example illustrates a specific kind of acid salt, an optically active acid addition salt, to resolve paroxetine into an optically pure form before forming the hydrochloride paroxetine salt. The example on pages 51-52 of Stemp fails to teach or suggest the generic concept of converting any organic acid salt of paroxetine into paroxetine hydrochloride, as the Examiner asserts, and actually teaches away from the Examiner's proposed modification. Methane sulfonic acid is not optically active and would not achieve resolution. Replacing the disclosed tartaric acid with methane sulfonic acid would destroy the purpose of the example and is manifestly an unobvious modification.

Secondly, the page 3 disclosure of Stemp does not suggest the Examiner's proposed modification of the paroxetine salt. The pharmaceutically acceptable salts recited on page 3 of Stemp are directed to the compounds of Stemp's formula (1), which compounds do not include paroxetine. Thus, the page 3 disclosure is irrelevant to paroxetine salts and to the pages 51-52 disclosure.

Thirdly, neither Barnes nor Stemp suggest paroxetine methane sulfonate, much less its use in the claimed process. Barnes' examples 2, 3, and 8 all use paroxetine acetate. Nothing is suggested in Barnes about using paroxetine methane sulfonate. Therefore, the Examiner again lacks motivation in the applied prior art to form the claimed process; i.e., no motivation to pick paroxetine methane sulfonate as the starting acid salt. Indeed, the mere fact that salts of paroxetine are known is not a suggestion of applicants' particular salt. *In re Jones*, 958 F.2d 347 (Fed. Cir. 1992).

Fourthly, claims 24 and 25 are directed to a process that uses a novel, patentable compound, namely paroxetine methane sulfonate¹ as a starting material. Because selecting paroxetine methane sulfonate was itself unobvious and hence patentable, it follows that any use of such a compound is likewise unobvious and patentable. See *In re Ochiai*, 37 USPQ2d 1127 (Fed. Cir. 1995)(all limitations must be considered in determining obviousness, including the specified starting material). Therefore, the claimed process, which uses an unobvious starting material, is patentable.

Given that Stemp and Barnes fail to teach or suggest the applicants' claimed starting material and further fail to teach or suggest contacting such a starting material with hydrochloric acid, the Examiner has failed to establish a *prima facie* case of obviousness. Accordingly reconsideration and withdrawal of this rejection are respectfully requested.

¹ The Examiner granted the grand-parent application, now US 5,874,447, which contains claims to, *inter alia*, paroxetine methane sulfonate.

CONCLUSION

In view of the above arguments, the presently claimed subject matter is novel and unobvious over the applied prior art. Reconsideration and withdrawal of the rejection and allowance of the present application are respectfully requested.

Should the Examiner have any questions regarding this application, she is encouraged to contact Mark R. Buscher (Reg. No. 35,006) at telephone No. 703 753 5256.

Respectfully submitted,



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